

110TH CONGRESS
2D SESSION

H. R. 6345

To establish a demonstration program to provide financial incentives to encourage the adoption and use of interactive personal health records and to encourage health information exchange networks to link clinical data to such personal health records.

IN THE HOUSE OF REPRESENTATIVES

JUNE 23, 2008

Mr. BOUSTANY introduced the following bill; which was referred to the Committee on Energy and Commerce, and in addition to the Committee on Ways and Means, for a period to be subsequently determined by the Speaker, in each case for consideration of such provisions as fall within the jurisdiction of the committee concerned

A BILL

To establish a demonstration program to provide financial incentives to encourage the adoption and use of interactive personal health records and to encourage health information exchange networks to link clinical data to such personal health records.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Patient-Controlled
5 Health IT Act”.

1 **SEC. 2. PERSONAL HEALTH RECORD (PHR) INCENTIVE**
2 **DEMONSTRATION PROGRAM.**

3 (a) ESTABLISHMENT.—Not later than one year after
4 the date of the enactment of this Act, the Secretary of
5 Health and Human Services (in this section referred to
6 as the “Secretary”) shall establish a demonstration pro-
7 gram (in this section referred to as the “demonstration
8 program”) in not more than 5 States to provide financial
9 incentives during a 5-year period for the use of qualifying
10 personal health records by qualifying patients and quali-
11 fying providers to—

12 (1) provide patients (or their authorized rep-
13 resentatives) access to and control over their per-
14 sonal health data so as to become healthier and
15 more informed and engaged health care consumers;

16 (2) make available to such qualifying providers
17 an accurate minimum data set of patient informa-
18 tion (as described in subsection (e)(1)(B)) at all
19 points of care;

20 (3) protect patient security and privacy, with
21 respect to their health care information;

22 (4) improve patients’ adherence to evidence-
23 based health care guidelines, medication guidelines,
24 preventive care, and screening protocols, thereby im-
25 proving health outcomes and lowering health care
26 costs;

1 (5) provide patients with more accurate, timely,
2 and appropriate information related to their health
3 care benefits and related administrative information;

4 (6) improve the quality and efficiency of com-
5 munication between health care providers and pa-
6 tients;

7 (7) create a direct communications channel to
8 patients in the event of emergencies;

9 (8) provide access with appropriate privacy
10 safeguards to de-identified health care information
11 to evaluate and advance public health and health re-
12 search goals; and

13 (9) incentivize health information exchange net-
14 works to plan for and implement methods to provide
15 patient access to clinical data through use of per-
16 sonal health records.

17 (b) INCENTIVE PAYMENTS.—

18 (1) IN GENERAL.—Under the demonstration
19 program, subject to paragraph (2), each qualifying
20 provider (as defined in subsection (c)) that furnishes
21 services to a qualifying patient (as defined in sub-
22 section (d)) and each health information exchange
23 network (as defined in subsection (g)) shall receive
24 an incentive payment, in accordance with this sub-

1 section, from the PHR Incentive Fund established
2 under subsection (i).

3 (2) ONE PAYMENT FOR PROVIDERS IN SAME
4 GROUP PRACTICE.—In the case of a qualifying pa-
5 tient who receives services during a fiscal year from
6 more than one qualified provider in the same group
7 practice, as defined by the Secretary, only one incen-
8 tive payment under paragraph (1) for such fiscal
9 year shall be made to such providers with respect to
10 such patient.

11 (3) AMOUNT OF INCENTIVE PAYMENT.—

12 (A) IN GENERAL.—Except as otherwise
13 provided, the amount of the incentive payment
14 under the demonstration program for a fiscal
15 year—

16 (i) paid to a qualifying provider shall
17 be—

18 (I) at least \$3 for each qualifying
19 patient not described in subclause
20 (II); and

21 (II) at least \$5 for each quali-
22 fying patient with a covered chronic
23 health condition described in subpara-
24 graph (C); and

1 (ii) paid to the health information ex-
2 change network shall be at least \$3 for
3 each qualifying patient for whom such net-
4 work facilitates under subsection (g)(2) ac-
5 cess to and retrieval of clinical data into a
6 qualifying personal health record.

7 (B) AUTHORITY TO INCREASE AMOUNT OF
8 INCENTIVE PAYMENTS.—The Secretary may in-
9 crease the amount of incentive payments de-
10 scribed in clause (i)(I), (i)(II) (including for the
11 case of qualifying patients with more than one
12 covered chronic health conditions described in
13 subparagraph (C)), or (ii) of subparagraph (A)
14 under the demonstration program for a fiscal
15 year so long as such increase will not result
16 in—

17 (i) the total amount of such incentive
18 payments under this paragraph (and the
19 costs of other permissible uses described in
20 subsection (i)(1) of funds in the PHR In-
21 centive Fund under subsection (i)) for such
22 fiscal year, exceeding

23 (ii) the total amount of funds in such
24 PHR Incentive Fund for such fiscal year.

1 (C) COVERED CHRONIC HEALTH CONDI-
2 TION DESCRIBED.—For purposes of subpara-
3 graph (A), a covered chronic health condition is
4 any of the following:

5 (i) Major mental disorder.

6 (ii) Diabetes.

7 (iii) Heart disease.

8 (iv) Asthma.

9 (v) Hypertension.

10 (vi) Cancer.

11 The Secretary, in consultation with the United
12 States Preventive Services Task Force convened
13 by the Public Health Service, may add to or
14 otherwise modify the list of covered chronic
15 health conditions specified under this subpara-
16 graph.

17 (D) AUTHORITY TO INCREASE AMOUNT OF
18 INCENTIVE PAYMENTS OR VARY INCENTIVES
19 ACCORDING TO PRACTICE SIZE AND GEO-
20 GRAPHIC LOCATION.—Subject to subparagraph
21 (B), the Secretary may increase the amount of
22 incentive payments described in clause (i)(I) or
23 (i)(II) of subparagraph (A) under the dem-
24 onstration program (or provide additional or
25 different incentives) for a fiscal year for quali-

1 fying providers specified by the Secretary as
2 providers with small practices and qualifying
3 providers located in rural areas.

4 (4) PUBLICATION OF NAMES OF QUALIFYING
5 PROVIDERS AND PATIENT AND PROVIDER EDU-
6 CATION ABOUT HEALTH INFORMATION EX-
7 CHANGE.—In order to assist patients in identifying
8 health care providers that use qualifying personal
9 health records, and to assist patients and health
10 care providers in understanding personal health
11 records and health information exchange networks,
12 under the demonstration program the Secretary
13 shall—

14 (A) provide for outreach activities, through
15 the use of local methods and Internet websites
16 of the Secretary's choosing, to provide patients
17 residing in a State participating in the dem-
18 onstration program with a list of qualifying pro-
19 viders who participate in the program;

20 (B) in consultation with appropriate orga-
21 nizations that represent health care consumers,
22 as well as organizations that represent health
23 information exchange organizations, provide for
24 activities to educate patients residing in a State
25 participating in the demonstration program

1 about the health and convenience benefits of
2 qualifying personal health records and the bene-
3 fits of electronic health information exchange
4 networks;

5 (C) provide for activities to educate quali-
6 fying providers about the patient, provider, and
7 overall health care benefits of using qualifying
8 personal health records and participating in
9 electronic health information exchange net-
10 works;

11 (D) in consultation with patient organiza-
12 tions, nongovernmental organizations, and other
13 agencies specified by the Secretary, provide for
14 activities that inform patients of the benefits
15 and risks associated with their use of health in-
16 formation technology and health information
17 exchanges, including the affect that such tech-
18 nology and exchanges may have on the quality
19 of care provided; and

20 (E) develop an interactive outreach and
21 education plan for patients and health care pro-
22 viders to communicate the benefits and risks of
23 health information technology and health infor-
24 mation exchanges, how to evaluate and use
25 health information tools and services, and how

1 patients could use such technology and ex-
2 changes to participate more completely in their
3 health care.

4 (c) QUALIFYING PROVIDER DEFINED.—For purposes
5 of this section, the term “qualifying provider” means a
6 licensed physician (or other licensed health care provider
7 designated by the Secretary) that meets the following re-
8 quirements, with respect to a qualifying patient of that
9 provider and the qualifying personal health record of that
10 patient:

11 (1) The physician (or provider), or authorized
12 representative, updates the diagnosis and medication
13 list (including all current medications and new medi-
14 cations prescribed) in the QPHR after each patient
15 encounter, if appropriate and as authorized by the
16 patient, either by direct entry or through a data
17 sharing arrangement using an appropriate electronic
18 means, such as an electronic medical record, e-pre-
19 scribing, or health information exchange network.

20 (2) To the extent authorized by the patient, the
21 physician (or provider), or authorized representative
22 ensures that the name of the physician (or provider)
23 is included in the QPHR of the patient on a list of
24 health care providers who furnish services to the pa-
25 tient.

1 (3) The physician (or provider), or authorized
2 representative complies with any security and pri-
3 vacy standards, policies, and practices described
4 under paragraphs (1), (2), and (3) of subsection (h).

5 (4) The physician (or provider), or authorized
6 representative meets other requirements as the Sec-
7 retary may establish.

8 (d) QUALIFYING PATIENT DEFINED.—For purposes
9 of this section, the term “qualifying patient” means an
10 individual—

11 (1) for whom a qualifying personal health
12 record has been established and is in operation
13 under the demonstration program; and

14 (2) who is a Medicare beneficiary or is covered
15 under a health benefits or other plan the sponsor of
16 which is participating as a Fund partner under sub-
17 section (i).

18 (e) QUALIFYING PERSONAL HEALTH RECORD DE-
19 FINED.—For purposes of this section, the terms “quali-
20 fying personal health record” and “QPHR” mean a record
21 of health care information, with respect to a patient, that
22 meets the following requirements:

23 (1) CONTENT.—

24 (A) IN GENERAL.—The record—

1 (i) shall contain at least the minimum
2 data set of patient information described in
3 subparagraph (B)(i); and

4 (ii) may consist of such additional
5 personal health information, such as family
6 health history, symptoms, use of over-the-
7 counter medication, diet, exercise, and
8 other relevant health information and ac-
9 tivities, as the patient may provide in ac-
10 cordance with paragraph (2)(A)(ii).

11 (B) MINIMUM DATA SET OF PATIENT IN-
12 FORMATION.—A minimum data set of patient
13 information described in this paragraph, with
14 respect to a qualifying patient and a qualifying
15 provider authorized by the patient to access the
16 QPHR of the patient, is a data set that is con-
17 sistent with the following:

18 (i) The data set includes—

19 (I) laboratory results in such a
20 format as to enable the patient and
21 qualifying provider to retrieve, store,
22 graph, and share the results as au-
23 thorized by the patient;

24 (II) a list of health conditions
25 and allergies as contained in records

1 of health providers involved in the
2 care of the patient (in such a format
3 as to enable the patient and qualifying
4 provider to retrieve and store lists of
5 current and previous health conditions
6 and allergies of the patient);

7 (III) diagnosis codes, with re-
8 spect to treatment for such a condi-
9 tion or allergy, in such a format as to
10 enable the patient and qualifying pro-
11 vider to retrieve and store a list of
12 such codes; and

13 (IV) an updated list of health
14 providers involved in the care of the
15 patient to enable the patient and
16 qualifying provider to communicate
17 information about the patient to any
18 provider on the list, as authorized by
19 the patient, for care coordination.

20 (ii) The data set provides for the abil-
21 ity to access the results, conditions, aller-
22 gies, diagnosis codes, and list described in
23 clause (i) in layperson terms.

1 (iii) The data set is portable and en-
2 ables the patient to move the data between
3 personal health records of the patient.

4 (2) ACCESS TO THE RECORD.—

5 (A) ACCESS RIGHTS OF PATIENT.—

6 (i) IN GENERAL.—Access to the
7 record (and each portion of the record)
8 shall be controlled solely by the patient (or
9 the patient's authorized representative),
10 with the patient (or the patient's author-
11 ized representative) able to access the
12 record through the Internet, print the
13 record, copy the record to electronic media,
14 and provide online access to authorized
15 third parties, including health care pro-
16 viders, to all individually identifiable health
17 information held in the record at any time,
18 in accordance with this paragraph.

19 (ii) ADDITION OF PERSONAL INFOR-
20 MATION.—The patient may add personal
21 health information to the record, except
22 that such patient shall not alter informa-
23 tion that is entered into the record by any
24 qualifying provider. Such patient shall have
25 the right to propose an amendment to in-

1 formation that is entered by a qualifying
2 provider pursuant to standards prescribed
3 by the Secretary for purposes of amending
4 such information.

5 (iii) IDENTIFICATION OF INFORMA-
6 TION ENTERED BY PARTICIPANT.—Any ad-
7 ditions or amendments made by the pa-
8 tient to the record shall be identified and
9 disclosed within such record as being made
10 by such patient.

11 (B) ACCESS BY AUTHORIZED INDIVIDUALS
12 OTHER THAN PATIENT.—

13 (i) AUTHORIZED ACCESS ONLY.—Ex-
14 cept as provided under subparagraphs (C)
15 and (D), access to the record (or any por-
16 tion of the record) by an individual other
17 than the patient (or the patient's author-
18 ized representative)—

19 (I) may be made only if the indi-
20 vidual is a health care provider who is
21 authorized by the patient to access
22 the record;

23 (II) may be made only to the
24 minimum data set of the patient (as
25 described in paragraph (1)(B)) and to

1 such other portions of the QPHR as
2 specified by the patient; and

3 (III) may be limited by the pa-
4 tient for purposes of entering informa-
5 tion into such record, retrieving infor-
6 mation from such record, or both.

7 (ii) IDENTIFICATION OF ENTITY THAT
8 ENTERS INFORMATION.—Any information
9 that is added by a qualifying provider to
10 the record shall be identified and disclosed
11 within such record as being made by such
12 provider. The record shall enable the pa-
13 tient to identify each individual that has
14 been authorized by the patient to access
15 the record, the portions of the record
16 accessed, and the date of such access.

17 (iii) NOTIFICATION OF LIMITED AC-
18 CESS TO RECORD.—In the case that the
19 patient (or the patient's authorized rep-
20 resentative) authorizes access by a health
21 care provider to only a portion of the
22 record and that portion does not include
23 the complete portion of the record, an indi-
24 cator shall be included in the record to
25 alert the provider that such authorized

1 portion is not representative of the com-
2 plete record relating to medications taken
3 by the patient.

4 (C) DEEMED AUTHORIZATION FOR ACCESS
5 FOR EMERGENCY HEALTH CARE.—With respect
6 to the record of the patient, the patient shall be
7 deemed as providing authorization (in the form
8 of affirmative consent) for health care providers
9 to access, in connection with providing emer-
10 gency care services to the patient, a limited, au-
11 thenticated information set concerning the pa-
12 tient for emergency response purposes, unless
13 the patient specifies that such information set
14 (or any portion of such information set) may
15 not be so accessed. Such limited information set
16 shall include the minimum data set of patient
17 information described in paragraph (1)(B) for
18 the patient and any other information specified
19 by the patient for such purposes.

20 (D) PUBLIC HEALTH ANALYSIS AND RE-
21 SEARCH.—

22 (i) IN GENERAL.—A QPHR service
23 provider operating or administering a
24 QPHR may provide data included in the
25 QPHR that has been de-identified con-

1 sistent with the applicable requirements of
2 section 164.514 of title 45, Code of Fed-
3 eral Regulations, for public health analysis,
4 post-market safety surveillance of prescrip-
5 tion drugs, and for research purposes.

6 (ii) REQUIRED CONSULTATION TO OP-
7 TIMIZE PUBLIC HEALTH CAPABILITIES.—

8 The Secretary shall consult with the Com-
9 missioner of the Food and Drug Adminis-
10 tration, the Director of the National Insti-
11 tutes of Health, the Director of the Cen-
12 ters for Disease Control and Prevention,
13 and the Administrator of the Agency for
14 Healthcare Research and Quality to opti-
15 mize the public health and post-market
16 surveillance capabilities of QPHRs.

17 (E) TERMINATION RIGHTS.—

18 (i) IN GENERAL.—The record shall
19 allow the patient (or the patient’s author-
20 ized representative) to terminate at any
21 time during or after the period of the dem-
22 onstration program—

23 (I) the further use of the QPHR
24 service provider operating or admin-
25 istering the record, including elimi-

1 nation of the patient's personal health
2 information in the control of the
3 QPHR service provider and including
4 in the case of a QPHR service pro-
5 vider that terminates its participation
6 in the demonstration program or
7 ceases to be a QPHR service provider;

8 (II) the further access to the
9 record by a qualifying provider; or

10 (III) the further use of a health
11 information exchange network.

12 (ii) CLARIFICATION.—Nothing in this
13 subparagraph shall require a health care
14 provider to eliminate a patient's personal
15 health information included in the QPHR
16 that is in a medical record maintained by
17 the provider.

18 (F) TRANSPORTABILITY.—The patient's
19 rights to control access to the record under this
20 paragraph shall not be affected by changes in
21 relationships with particular providers or health
22 plans.

23 (3) SECURITY.—The record shall at least meet
24 minimum security standards, including the regula-
25 tions promulgated under section 264(c) of the

1 Health Insurance Portability and Accountability Act
2 of 1996 (HIPAA) (42 U.S.C. 1320d–2 note) and
3 other such minimum standards as identified by the
4 Secretary under subsection (h).

5 (4) WEB-BASED.—The record shall be web-
6 based.

7 (5) AUTHENTICATION.—The record shall in-
8 clude functionality to authenticate the patient’s iden-
9 tity prior to the record’s use to receive electronic
10 data of personal health information (other than ac-
11 tual authentication information) from third party
12 sources, such as health information exchange net-
13 works, pharmacies, pharmacy benefit managers, lab-
14 oratories, and health plans, including the Medicare
15 program.

16 (f) QPHR SERVICE PROVIDER.—

17 (1) DEFINITION.—For purposes of this section,
18 the term “QPHR service provider” means an entity
19 that—

20 (A) operates or administers a QPHR or
21 part of a QPHR;

22 (B) has access to patients’ individually
23 identifiable health information contained in the
24 QPHR;

1 (C) complies with any security and privacy
2 standards, policies, and practices adopted under
3 subsection (h);

4 (D) not later than the date that is one
5 year after the date of the enactment of this Act,
6 is able to exchange standards-based clinical and
7 patient data with other sources and users of
8 health data, including other QPHRs and health
9 information exchange organizations;

10 (E) is capable of exchanging information
11 with a health information exchange network
12 and is capable of sharing such information be-
13 tween the patient involved and the health care
14 providers of such patient and enabling patient-
15 provider communication; and

16 (F) meets the messaging requirements de-
17 scribed in paragraph (2) and disclosure require-
18 ment described in paragraph (3).

19 (2) MESSAGING REQUIREMENTS.—

20 (A) IN GENERAL.—Subject to subpara-
21 graph (B), the messaging requirements de-
22 scribed in this paragraph, with respect to a
23 QPHR service provider that operates or admin-
24 isters a QPHR, are the following:

1 (i) EDUCATION REMINDERS.—Subject
2 to clause (v), the QPHR service provider
3 shall have the capability of sending pa-
4 tient-specific patient education messages,
5 reminders, and clinical messages to quali-
6 fying patients based upon data in the
7 QPHR.

8 (ii) FEDERAL REMINDERS.—Subject
9 to clause (v), the QPHR service provider
10 shall provide for the sending on behalf of
11 Federal agencies of objective, accurate, pa-
12 tient-specific messages to qualifying pa-
13 tients concerning their health care or bene-
14 fits.

15 (iii) FUND PARTNER MESSAGES.—
16 Subject to clause (v), the QPHR service
17 provider shall provide for the sending, on
18 behalf of Fund partners who contribute to
19 the Fund, appropriate patient-specific mes-
20 sages to qualifying patients (with whom
21 such partners have pre-existing relation-
22 ships) concerning the patients' health care,
23 medications, treatments, medical devices or
24 benefits. The QPHR service provider shall
25 not allow a Fund partner to send a mes-

1 sage to a patient about a product or serv-
2 ice unless that product or service has al-
3 ready been prescribed or recommended to
4 the patient by a health care provider.

5 (iv) PATIENT OPT-IN.—

6 (I) IN GENERAL.—Subject to
7 subclause (II), the QPHR service pro-
8 vider shall not allow messages to be
9 sent to a patient unless the provider
10 has requested and received the per-
11 mission of the patient (or patient’s
12 authorized representative).

13 (II) OPT-OUT.—A patient may at
14 any time opt out of receiving mes-
15 sages entirely or from a particular
16 source.

17 (v) LIMITATION ON COMMERCIAL SO-
18 LICITATION.—The QPHR service provider
19 shall not allow messages to be sent to a
20 patient unless—

21 (I) the patient is a patient or
22 beneficiary of the sender or source of
23 the message, uses the sender’s or
24 source’s product with a prescription
25 or recommendation of a provider, or

1 has some other health-related pre-ex-
2 isting relationship (as defined by the
3 Secretary) with the sender or source,
4 or the sender or source is a public
5 health agency;

6 (II) the message contains infor-
7 mation directly related to the patient's
8 health or health care and does not in-
9 clude marketing or commercial solici-
10 tations;

11 (III) the message complies with
12 standards adopted under subsection
13 (h)(4); and

14 (IV) the message clearly identi-
15 fies the source of the content and the
16 sender of the message.

17 (vi) HEALTH PLAN NOTIFICATION.—
18 The QPHR service provider shall notify,
19 no less frequently than quarterly, each
20 Fund partner that operates a health ben-
21 efit plan of the individuals who have re-
22 ceived messages sent on behalf of the Fund
23 partner under this section.

24 (B) ALTERNATIVE REQUIREMENTS.—For
25 purposes of paragraph (1)(F), the Secretary

1 may develop and specify requirements that a
2 QPHR service provider may meet instead of the
3 requirements described in subparagraph (A) so
4 long as such requirements provide for a method
5 and incentives for private entities to contribute
6 to the PHR Incentive Fund.

7 (3) DISCLOSURE REQUIREMENT.—The disclo-
8 sure requirement described in this paragraph with
9 respect to a QPHR service provider is that at the
10 time of entering into an arrangement with an indi-
11 vidual to operate or administer a QPHR (or part of
12 a QPHR) of the individual, the QPHR service pro-
13 vider shall provide to the individual a notice of the
14 privacy policies of the QPHR service provider, which
15 shall be presented in a clear and understandable
16 manner, meet such standards as specified by the
17 Secretary of Health and Human Services and the
18 Secretary of Commerce, and include the following:

19 (A) ASSURANCES NOT TO SELL INDIVID-
20 UALLY IDENTIFIABLE INFORMATION.—Assur-
21 ances, in a form and manner specified by the
22 Secretaries, that—

23 (i) the QPHR service provider will not
24 sell any individually identifiable health in-
25 formation of such individual and the

1 QPHR service provider will not sell or
2 share any such information of such indi-
3 vidual for the purposes of marketing or de-
4 cisions related to employment or financial
5 services; and

6 (ii) the QPHR service provider will
7 disclose to the individual any possible sec-
8 ondary users of the individually identifiable
9 health information of such individual, in-
10 cluding business associates of the service
11 provider who may have access to such in-
12 formation, and the purpose for such use or
13 access.

14 (B) FUND PARTNER INFORMATION.—In-
15 formation identifying the Fund partners on be-
16 half of which the QPHR service provider sends
17 messages under paragraph (2)(C) and the types
18 of information that would potentially be avail-
19 able to such Fund partners.

20 (g) HEALTH INFORMATION EXCHANGE NETWORK
21 DEFINED.—For purposes of this section, the term “health
22 information exchange network” means any State-based or
23 local entity—

1 (1) the governance of which formally involves
2 health care consumers, employers, health plans, hos-
3 pitals, and practicing clinicians;

4 (2) which facilitates private and secure access
5 to and retrieval of clinical data, including laboratory
6 test results and medication-related information, to
7 provide safer, more timely, efficient, effective, and
8 equitable patient-centered care;

9 (3) which meets data standards for interoper-
10 ability, as specified by the Secretary;

11 (4) which meets applicable requirements for pri-
12 vacy, confidentiality, and security as specified by the
13 Secretary, including requirements and standards de-
14 scribed in subsection (h); and

15 (5) that provides to each patient participating
16 in such network (at the initiation of such participa-
17 tion) a notice of the privacy policies and other con-
18 sumer protection policies of the network, which shall
19 be presented in a clear and understandable manner
20 and meet such standards as specified by the Sec-
21 retary of Health and Human Services and the Sec-
22 retary of Commerce and include assurances, in a
23 form and manner specified by the Secretaries,
24 that—

1 (A) the entity will not sell any individually
2 identifiable health information of such indi-
3 vidual and the entity will not sell or share any
4 such information of such individual for the pur-
5 poses of marketing or decisions related to em-
6 ployment or financial services; and

7 (B) the entity will disclose to the individual
8 any possible secondary users of the individually
9 identifiable health information of such indi-
10 vidual, including business associates of the serv-
11 ice provider who may have access to such infor-
12 mation, and the purpose for such use or access.

13 (h) PRIVACY AND CONSUMER PROTECTION STAND-
14 ARDS.—

15 (1) SECURITY AND PRIVACY STANDARDS, POLI-
16 CIES, AND PRACTICES.—For purposes of the dem-
17 onstration program, the security and privacy stand-
18 ards, policies, and practices described in this para-
19 graph include—

20 (A) the standards required under regula-
21 tions promulgated under section 264(c) of the
22 Health Insurance Portability and Accountability
23 Act of 1996 (HIPAA);

1 (B) standards to require plain language
2 notice of patients' rights with respect to per-
3 sonal health records; and

4 (C) any additional standards specified by
5 the Secretary to optimally protect and safe-
6 guard patient health care information, as long
7 as such standards are consistent with the
8 standards described in subparagraph (A).

9 (2) NOTIFICATION OF BREACH.—

10 (A) IN GENERAL.—In accordance with the
11 minimum criteria established under subpara-
12 graph (B), a QPHR service provider must dis-
13 close any breach of the security of individually
14 identifiable health information contained in a
15 QPHR to any individual whose individually
16 identifiable health information was, or is rea-
17 sonably believed to have been, acquired by an
18 unauthorized person and to the Secretary in a
19 manner specified by the Secretary.

20 (B) MINIMUM CRITERIA.—The Secretary,
21 in consultation with relevant agencies and ap-
22 propriate entities in the private sector, shall es-
23 tablish minimum criteria for which notifications
24 of wrongful disclosures are required under sub-
25 paragraph (A).

1 (3) AVAILABILITY OF INDIVIDUAL HEALTH IN-
2 FORMATION IN ELECTRONIC FORM.—Effective begin-
3 ning on January 1, 2010, an individual who requests
4 a copy of the individual’s individually identifiable
5 health information pursuant to the HIPAA regula-
6 tions referred to in paragraph (1) shall be entitled
7 to receive that information in electronic form capa-
8 ble of being imported into a QPHR, if such informa-
9 tion is maintained in electronic form by the entity
10 from which the information is requested.

11 (4) MESSAGE STANDARDS.—The Secretary
12 shall establish minimum standards to ensure the ob-
13 jectivity, accuracy, and relevance of messages sent to
14 individual patients under subsection (f)(2) from a
15 QPHR and to protect against the use of such mes-
16 sages by Fund partners for commercial solicitations
17 or marketing. Such standards shall incorporate ex-
18 isting standards governing communications to con-
19 sumers established by the Food and Drug Adminis-
20 tration, the Federal Trade Commission, or other
21 Federal agencies.

22 (i) PHR INCENTIVE FUND.—

23 (1) IN GENERAL.—The Secretary shall establish
24 a PHR Incentive Fund (in this section referred to
25 as the “PHR Incentive Fund” or “Fund”). The

1 Fund may receive contributions from Fund partners
2 for the sole purpose of paying PHR incentives under
3 the demonstration program, conducting the study
4 under subsection (j), and otherwise carrying out the
5 demonstration program.

6 (2) FUND PARTNERS.—

7 (A) IN GENERAL.—The Secretary may
8 enter into contracts with public or private pay-
9 ers, drug manufacturers, device manufacturers,
10 or other public or private entities (in this sec-
11 tion referred to as “Fund partners”) to allow
12 the Fund to receive contributions in accordance
13 with this subsection and other terms deter-
14 mined by the Secretary.

15 (B) FEDERAL PARTNERS.—The Secretary
16 shall seek the involvement and contributions of
17 the Food and Drug Administration, the Centers
18 for Disease Control and Prevention, the Agency
19 for Healthcare Research and Quality, and the
20 Department of Homeland Security to maximize
21 the effectiveness of the QPHRs in meeting the
22 health, national security, emergency response,
23 biosurveillance, and research goals of the Fed-
24 eral government in a manner consistent with
25 this section. A Federal agency described in the

1 previous sentence is authorized to make a con-
2 tribution to the Fund to the extent provided in
3 appropriation Acts.

4 (C) PARTNER ACCOUNTS.—

5 (i) IN GENERAL.—The Fund shall in-
6 clude an account for each Fund partner,
7 including the Medicare program, separately
8 accounting for each Fund partner's con-
9 tributions to the Fund. Contribution levels
10 under subparagraph (D) shall be made to
11 each account at the beginning of each fis-
12 cal year of the demonstration program for
13 incentive payments under this section for
14 services furnished during such fiscal year.
15 Incentive payments shall be debited from
16 each account in accordance with this sub-
17 section.

18 (ii) REMAINING AMOUNTS.—Amounts
19 in the account of a Fund partner that are
20 not paid in a fiscal year (before the last
21 fiscal year of the demonstration program)
22 shall remain available for payment from
23 such account in the subsequent fiscal year.
24 Amounts in the account of a Fund partner
25 that are not paid in the last fiscal year of

1 the demonstration program shall be re-
2 funded to the Fund partner.

3 (D) CONTRIBUTION LEVELS.—Contribu-
4 tion levels to the Fund by Fund partners shall
5 be set annually, by the Secretary, except that
6 the contribution level for the first year shall be
7 as follows:

8 (i) MEDICARE CONTRIBUTION.—The
9 Secretary shall contribute—

10 (I) \$3 for each qualifying patient
11 described in subsection (b)(3)(A)(i)(I),
12 with respect to a qualifying provider,
13 who is a Medicare beneficiary for
14 whom any PHR incentive payment
15 may be made under subsection (b)(1)
16 during such fiscal year to such pro-
17 vider;

18 (II) \$5 for each qualifying pa-
19 tient described in subsection
20 (b)(3)(A)(i)(II), with respect to a
21 qualifying provider, who is a Medicare
22 beneficiary for whom any PHR incen-
23 tive payment may be made under sub-
24 section (b)(1) during such fiscal year
25 to such provider; and

1 (III) \$3 for each qualifying pa-
2 tient who is a Medicare beneficiary for
3 whom an incentive payment may be
4 made under subsection (b)(1) during
5 such fiscal year to a health informa-
6 tion exchange network.

7 The contribution amounts described in this
8 clause shall be transferred from the Fed-
9 eral Hospital Insurance Trust Fund (es-
10 tablished under section 1817 of the Social
11 Security Act) and from the Federal Sup-
12 plementary Medical Insurance Trust Fund
13 (established under section 1841 of such
14 Act) in such proportion as the Secretary
15 may specify.

16 (ii) OTHER PAYER CONTRIBUTIONS.—
17 Any Fund partner that is a health care
18 payer other than the Medicare program
19 (and is not an agency described in sub-
20 paragraph (B)) shall contribute—

21 (I) at least \$3 for each qualifying
22 patient described in subsection
23 (b)(3)(A)(i)(I), with respect to a
24 qualifying provider, who is covered
25 under a health benefits or other plan

1 the sponsor of which is the Fund
2 partner and for whom a PHR incen-
3 tive payment may be made under sub-
4 section (b)(1) during the fiscal year to
5 such provider;

6 (II) at least \$5 for each quali-
7 fying patient described in subsection
8 (b)(3)(A)(i)(II), with respect to a
9 qualifying provider, who is covered
10 under a health benefits or other plan
11 the sponsor of which is the Fund
12 partner and for whom a PHR incen-
13 tive payment may be made under sub-
14 section (b)(1) during the fiscal year to
15 such provider; and

16 (III) at least \$3 for each quali-
17 fying patient who is covered under a
18 health benefits or other plan the spon-
19 sor of which is the Fund partner and
20 for whom an incentive payment may
21 be made under subsection (b)(1) dur-
22 ing such fiscal year to a health infor-
23 mation exchange network.

24 (iii) MESSAGING CONTRIBUTIONS.—

1 (I) IN GENERAL.—Subject to
2 subclause (II), the Secretary may es-
3 tablish contribution levels for Fund
4 partners that employ messages sent
5 under subsection (f)(2)(C) in the fis-
6 cal year.

7 (II) FDA-MESSAGING CONTRIBU-
8 TIONS.—The amount of the contribu-
9 tion of a drug manufacturer that is a
10 Fund partner is equal to at least \$3
11 for each qualifying patient for each
12 medication adherence program for
13 which one or more messages are sent
14 under subsection (f)(2)(C) in the fis-
15 cal year.

16 (E) DEBITING FUND PARTNERS' AC-
17 COUNTS.—The Medicare program's account
18 shall be debited for each incentive payment
19 made under subsection (b)(1), with respect to a
20 qualifying patient who is a Medicare bene-
21 ficiary. Each other Fund partner's account
22 shall be debited for each incentive payment
23 made under subsection (b)(1), with respect to a
24 qualifying patient who is covered under a health
25 benefits or other plan the sponsor of which is

1 such Fund partner. Each Fund partner's ac-
2 count shall be debited for messages sent under
3 subsection (f)(2)(C) for such partner in accord-
4 ance with a methodology specified by the Sec-
5 retary. In the event that a Fund partner's ac-
6 count does not have a sufficient balance to
7 cover the Fund partner's liability, the Fund
8 partner shall make a supplemental contribution
9 to the Fund to cover the shortfall.

10 (F) LIMITATION ON BENEFITS.—Contribu-
11 tions by a Fund partner to the Fund shall con-
12 fer no preferential access to data or information
13 or any other benefit to the partner other than
14 public acknowledgment under paragraph (3)
15 and the ability to have messages sent to quali-
16 fying patients under subsection (f)(2)(C).

17 (3) PUBLICATION OF FUND CONTRIBUTORS.—

18 The Secretary shall publish on the official public
19 website of the Centers for Medicare & Medicaid
20 Services a list of Fund partners that have contrib-
21 uted to the Fund.

22 (j) STUDY AND REPORTS.—

23 (1) INTERIM REPORT.—Not later than 3 years
24 after the initiation of the demonstration program,
25 the Secretary shall submit to Congress a report on

1 the following, with respect to the demonstration pro-
2 gram:

3 (A) The extent to which privacy protec-
4 tions are sufficient under the demonstration
5 program and recommendations for any addi-
6 tional privacy protections that may be nec-
7 essary.

8 (B) The extent to which use of data in
9 QPHRs by qualifying providers varies based on
10 the size of the practice of the qualifying pro-
11 viders and based on whether the qualifying pro-
12 viders are located in a rural or urban area.

13 (C) The effectiveness of patient and pro-
14 vider outreach and education efforts to increase
15 the utilization and utility of QPHRs.

16 (D) The measurable benefits and concerns
17 of qualifying providers, with respect to use of
18 QPHRs and potential adoption of personal
19 health record technology.

20 (2) STUDY AND FINAL REPORT.—

21 (A) STUDY.—At the conclusion of the
22 demonstration program, the Secretary shall
23 provide for a study to assess the level of pa-
24 tients' use of their QPHR, the type of data
25 transmitted by health information exchange

1 networks, the impact of the standards used in
2 transmitting the data, the utility of such data
3 to health care providers in delivering patient
4 care and to patients in managing their health
5 (including adherence to prescribed medications
6 and recommended preventive care), any changes
7 in health outcomes, and any cost savings result-
8 ing from implementation of the program. The
9 study shall include collection of aggregate data
10 documenting the number of qualifying patients,
11 the number of providers using the QPHR, the
12 number of patients using the QPHR, the type
13 of data presented in the QPHR, and other
14 measures of the program's effectiveness.

15 (B) FINAL REPORT.—Not later than 2
16 years after the last day of the demonstration
17 program, the Secretary shall submit to Con-
18 gress a report on the results of the study under
19 paragraph (1).

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